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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,011	04/20/2000	Natarajan Ranganathan	KBI-0003	6238

7590 07/16/2002
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66 E Main Street
Marlton, NJ 08053

EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/16/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,011

Applicant(s)

Ranganathan et al.

Examiner

Patricia Patten

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 29, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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DETAILED ACTION

Claims 1-4 are pending in the application and were presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yatzidis et al. (1979) in view of Prakash et al. (1995) and further in view of Goldenhersh et al. (1976). Claims 1-4 are drawn to a microencapsulated formulation comprising a mixture of sorbents and a bacterial source, wherein the sorbents have absorption affinities for substances such as ammonia, urea, creatine, phenols and indoles. Claims are further drawn to where the composition comprises a phosphate binding agent and a water binding agent.

Yatzidis et al. (1979) disclosed that locust bean gum showed a beneficial effect on patients with renal failure (uremia). Locust bean gum was shown to have the ability to absorb urea, creatine, uric acid, ammonia phosphorus, chloride and sodium (pp.105). Locust bean gum also 'adsorbs about 10 times its own weight in water' (instant specification pp.4, lines 14-15). Yatzidis et al. did not specifically mention the combination of locust bean gum with a bacterium.

Prakash et al. (1995) disclosed a method for treating uremia by use of a microencapsulated *E.coli* strain (DH5) (Please see Abstract). They explained that the *E.coli* cells

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'efficiently depleted urea' (pp.625 Col.1)) and further indicated that the same bacteria lowered overall ammonia levels (pp.625 Col.2).

Goldenhersh et al. (1976) disclosed the need for more effective carbon detoxification such as in uremia. Upon studying the effects of in-vivo charcoal absorbency, Goldenhersh et al. discovered that there was a severe 'adsorption competition which interfered with adsorption of creatine on activated carbon'(pp.252 Col.2). And thus "...ingestion of a reasonable amount of unencapsulated activated carbon to remove creatinine would be of little value" (p.253, col.1). They consequently found that a microencapsulated form of activated charcoal resulted in required less of an amount of the charcoal being administered (pp.253, col.1).

One of ordinary skill in the art would have been motivated to have microencapsulated the composition comprising bacteria and absorbents because microencapsulation would have resulted in a lesser quantity of absorbents being used due to inhibitory mechanisms as discussed by Goldenhersh et al. It was further known that microencapsulated bacterium had a longer lasting effect as taught by Prakash et al.; hence, the ordinary artisan would have reasonably ascertained that a formulation for treating uremia had an improved beneficial effect when it was microencapsulated due to the competitive aspects in biological fluid.

Further, because all of the instantly claimed ingredients were known in the art for treating uremia separately, one of ordinary skill in the art would have had a reasonable expectation that the combination of the ingredients would have provided an additive affect on the ailment of

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uremia. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to treat uremia. This rejection is based on the well established proposition of patent law that **no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.**

Here, the Examiner is **relying upon case law in order to establish a prima facie case of obviousness.** Although the references themselves may not indicate a motivation to combine the Instantly claimed ingredients, the MPEP states 'The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; **the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (MPEP 2114).**

Applicants' arguments presented 4/29/02 (Paper No. 16) were fully considered, however, arguments pertaining to limitations which were deleted from the claimed language; namely, the recitation of a particular 'gut clearance rate' are moot. Arguments pertaining to the new language 'microencapsulated and enteric coated..' will be answered *infra*.

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Although Goldenhersh et al. and Prakash et al. did not specifically teach both microencapsulation *and* enteric coating *respectively*, Goldenhersh et al. did teach microencapsulation *with* enteric coatings (i.e., cellulose acetate). Thus, the charcoal composition *was* microencapsulated as well as enterically coated, thus obviating the new limitation to the claims.

Alternatively, it would not have required a substantial inventive contribution from one of ordinary skill in the art to have optimized the type of coating added to the composition. For example, one of ordinary skill in the art would have expected that an additional coating on the already enterically coated capsule would have afforded more protection from intestinal fluids for the constituents inside the capsule, thereby allowing delivery of said sorbents farther down the intestinal tract.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

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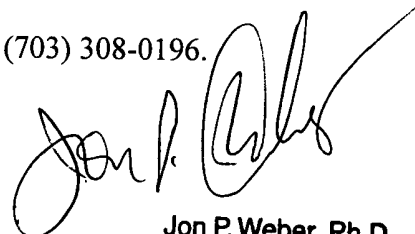
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.
Primary Examiner